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51
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,001	05/21/1999	ROGER V. KENDALL	FSC-6	7220
23599	7590	12/12/2003		
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
			EXAMINER EWOLDT, GERALD R	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/316,001	KENDALL ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18, 20-21, 38-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Remarks, filed 9/17/03, are acknowledged.
2. Claims 12-18, 20-21, and 38-46 are being acted upon.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
4. Claims 12-18, 20-21, and 38-46, stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,728, (of record) in view of Caughey et al. (of record) or Gibson et al. (of record) or U.S. Patent No. 4,455,298 (of record), for the reasons set forth in Papers No. 10, 17, 22, 26, and 33, mailed 9/26/00, 8/14/01, 3/22/02, 10/17/02, and 6/17/03, respectively.

Applicant arguments, filed 9/17/03, have been fully considered but are not found persuasive. Applicant reiterates the argument that "Applicants maintain their position that the original data of record in the specification supplemented with further proof of unexpected advantages in the previously submitted Declaration of Dr. John Lawson show unexpected, advantageous properties representative of the full scope of the claimed subject matter and, thus, provide clear and convincing evidence of the nonobviousness of the claimed invention. The data as a whole establish that the combination of DMG and Perna provides a significant and unexpected advantageous result over what would have been expected from the prior art teachings pertaining to the use of either DMG or Perna alone."

It remains the Examiner's position that any perceived unexpected advantages of the claimed composition do not outweigh the evidence as to the composition's obviousness. As set forth in MPEP 2144:

"The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their

combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983)."

It is the Examiner's position that sound scientific reasoning would have led a skilled artisan at the time of the invention to believe that a combination of known anti-inflammatory compositions would be expected to produce an improved anti-inflammatory composition.

Applicant argues "The Examiner alleges that the data in the Lawson Declaration cannot be considered to show nonobviousness because the data was generated after the invention was made. This position is completely contrary to the established law and PTO practice. The law clearly allows for - and mandates consideration of - data generated after filing which shows the properties of compositions supported by the disclosure."

It is the Examiner's position that the methods used in the Inventor's post-filing work were not "discounted", but rather said methods are not the methods used in the specification. In particular, the Inventor used dosages of composition that were not disclosed in the experiments of the specification. Note that Applicant has not disputed (nor even commented on) this fact. Additionally, should any unexpected results be established, said results could only pertain to the disclosed dosage and not to the broad ranges of dosages of the instant claims. Accordingly, it remains the Examiner's position that the scope of the claims is not commensurate with the scope of the data provided by Applicant asserting unexpected results.

Applicant argues "Kendall '728 provides a broad generic teaching which includes lupus in a list of autoimmune diseases treatable using DMG. But the secondary references directed to the use of Perna provide no suggestion to use Perna for treating lupus or that Perna would effect the kind of immune response shown by applicants. The allegation in the Office Action that it is well-known that SLE is often treated with anti-inflammatories and, thus, it would be obvious that Perna would be effective to treat SLE is unsupported on the record."

It remains the Examiner's position that one of skill in the art would have known that SLE is routinely treated with anti-inflammatory drugs. It is also noted that the Caughey et al. reference teaches the use of perna "as both a supplement and an alternative to orthodox anti-inflammatory medication" in RA. Thus, it remains the Examiner's position that it is not great jump to use perna as a supplement or alternative treatment for the inflammation associated with SLE.

Applicant argues "Applicants have shown that their novel combination provides significant and advantageous properties that would not have been expected by one of ordinary skill in the art for such combination. Accordingly, applicants have provided an advance in the art which is deserving of patent protection."

It seems to the Examiner's that the preceding assertion is somewhat confusing. Applicant appears to now be arguing novelty, while at the same time maintaining the argument of unexpected results. It remains the Examiner's position that the instant composition is neither novel nor has Applicant demonstrated unexpected results commensurate with the scope of the claims.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-18, 20-21, 38-43, and newly added Claims 44-46, stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, in Claims 12 and 15, the phrase "suitable for enteral but not parenteral administration" for the reasons set forth in Paper No. 26 and 33, mailed 10/17/02 and 6/17/03, respectively.

Applicant arguments, filed 9/17/03, have been fully considered but are not found persuasive. Applicant argues that the specification supports enteral, not enteral, parenteral, and not parenteral.

It remains the Examiner's position that the disclosure of enteral and parenteral is insufficient to support claims drawn to not enteral and not parenteral because, as set forth previously, the enteral and parenteral subgenuses are not mutually exclusive.

Regarding the opinions of the Inventors as set forth in their 1.132 declaration, the declarations say what they say. Inventor Kendall stated, "The following statements are not made as an expert in the field of the invention claimed in the above-identification application." This statement appears relatively clear - the Inventor does not consider himself to be an expert.

Regarding the declaration of Inventor Lawson, he states, "I have read the Declaration of my co-inventor. Dr. Roger V. Kendall, signed June 18 2002, and submitted earlier in the prosecution of this application. I concur with the statements made therein and also independently conclude that one of ordinary skill in the art at the time of our invention, upon reading our application, would find a description in the application of compositions of DMG and Perna both in a form suitable for enteral but not parenteral administration." Again, the declaration is clear; the second Inventor is merely expressing his opinion that he agrees with the first Inventor. While he does additionally state that he "independently concludes" the same thing, he provides no arguments whatsoever and thus, provides little additional strength to the argument of the first Inventor.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Serial No. 09/316,001
Art Unit 1644

6

Please Note: inquiries of a general nature or relating to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600


12/8/03
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER